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Attention: Desk Officer for EPA

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Enforcement & Compliance Docket
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Docket Officer, Docket No. EC-2000-007
Enforcement and Compliance Docket and Information Center
Room 4033
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Re: ICR 2002.02, EPA Proposed Rule, Establishment of Electronic Reporting; Electronic Records

Dear Sir or Madam:

The Dow Chemical Company ("Dow") welcomes the opportunity to comment on Information Collection Request ("ICR") 2002.02 concerning EPA's proposed Cross-Media Electronic Reporting and Recordkeeping Rule ("CROMERRR"), 66 Fed. Reg. 46162 (Aug. 31, 2001). Dow is a major manufacturer of chemicals and plastics, with many facilities in the United States that are subject to EPA recordkeeping requirements. Dow would be directly affected by CROMERRR if adopted.

EXECUTIVE SUMMARY

EPA appears not to have recognized the actual scope of the recordkeeping provisions of CROMERRR, and accordingly has not presented an accurate picture of the paperwork burden associated with those provisions. The key issue is whether, in practical effect, the recordkeeping provisions are or are not voluntary. The proposed rule and the ICR predict significant but acceptable burdens from the recordkeeping provisions because they are thought to be voluntary. Dow believes that they are not voluntary in any meaningful sense; that over a million facilities regulated by EPA would be affected; that current recordkeeping practices would be disrupted; and that each affected facility would have to

spend thousands of hours and many thousands or even millions of dollars to come into compliance.

The disparity between EPA's perspective and Dow's perspective is so great that it is not a matter of debating cost estimates. Instead, this is a fundamental gap in perspective. For the reasons presented below, Dow believes that EPA has failed to recognize just what it is asking of American industry. This is a far-reaching proposal which could impose many millions of dollars in added costs for EPA compliance.

As a result of its perspective, EPA has estimated the number of facilities affected by the recordkeeping requirements at 428 per year. Dow believes that the accurate number is about 1.2 million.

EPA admits that the costs of the recordkeeping requirements would exceed their benefits. It estimates the per-facility start-up costs to be $40,000 and the annual costs thereafter to be $17,000. It estimates the benefits to be $23,000. Thus, EPA can only justify the electronic recordkeeping requirements as a voluntary program. Dow believes that those requirements would not be voluntary and that the costs per facility would be potentially over $1,000,000.

EPA has estimated that the CROMERRR recordkeeping provisions would have no effect on small business. For that reason EPA did not conduct a Regulatory Flexibility Analysis. Dow believes that those provisions would have a substantial effect on small business.

EPA has stated that electronic recordkeeping to meet EPA recordkeeping requirements may not begin until EPA publishes a Federal Register notice to that effect, at some point in the future. Yet industry has been keeping EPA-mandated records electronically for years, and some EPA regulations explicitly allow electronic recordkeeping. Others are at least media-neutral, thus implicitly authorizing electronic recordkeeping. The effect of CROMERRR would be to shut down current recordkeeping practices across the United States, and to effectively amend current recordkeeping regulations.

EPA has stated that CROMERRR's stringent security provisions are necessary to deter and prosecute fraud for all EPA recordkeeping requirements. In doing so, EPA apparently failed to take into consideration OMB's directive under the Government Paperwork Elimination Act ("GPEA")[1] that electronic recordkeeping and reporting provisions not be a "one size fits all" approach. OMB directed agencies to weigh the risks of fraud and the costs and benefits of various approaches to handling security of electronic information under the GPEA. CROMERRR reflects a decision by EPA to impose close to the maximum security protections on even the least important of EPA's many recordkeeping requirements. This would have the effect of deterring, not encouraging, electronic recordkeeping, contrary to the purpose of GPEA.

[1] Pub. L. No. 105-277, Title XVII (Oct. 21, 1998).

EPA has not devoted the necessary resources to analyzing the effects of CROMERRR on recordkeeping by regulated facilities. The public docket for this rulemaking has information on the costs to EPA of electronic recordkeeping, and on the costs to the regulated community of electronic reporting. There is virtually nothing in the docket addressing the costs to the regulated community of electronic recordkeeping. Instead, EPA has promised to conduct research on those costs.

Electronic reporting would be a new activity which would be voluntary; regulated facilities could decide whether or not to switch from paper-based reporting to electronic reporting, based on their own assessments of the relative costs and benefits of each. But electronic recordkeeping is not a new activity and it is no longer voluntary; rather, it is an integral part of how recordkeeping is done today. Accordingly, it is impossible for most regulated facilities to meet EPA recordkeeping requirements other than with the use of computers. That means that CROMERRR would effectively mandate the retrofitting or replacement of over a million computer systems throughout American industry, at a cost of many millions or billions of dollars. EPA has failed to appreciate, or justify, such a cost.

OMB should not approve the ICR for CROMERRR. It should direct EPA to withdraw the proposal, re-analyze its approach to electronic recordkeeping, conduct appropriate cost-benefit and small business impact analyses, and re-propose a rule which reflects the realities of today's electronic workplace.

DISCUSSION

1. EPA Considers the Paperwork Burdens of CROMERRR's Recordkeeping Provisions to be Significant But Acceptable Because the Provisions Are Seen as Voluntary.

EPA's supporting statement for ICR 2002.02[2] presents EPA's key understanding of CROMERRR:

> Under the proposed rule, electronic document submission or electronic recordkeeping would be totally voluntary; EPA would not require the submission of electronic documents or maintenance of electronic records in lieu of paper documents or records.[3]

From this understanding that the recordkeeping provisions are voluntary flows EPA's estimation of the associated paperwork burdens:

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[2] EPA, "Supporting Statement for Information Collection Request Number 2002.02 'Electronic Reporting and Recordkeeping—Proposed Rule'" (not dated) ("Supporting Statement").
[3] Supporting Statement at 1.

> Further, electronic . . . recordkeeping would be voluntary and would likely only be used by facilities only if cost-effective and non-duplicative with their other compliance activities.[4]
>
> EPA estimates that, on average, 428 facilities will acquire and install electronic recordkeeping systems annually.[5]
>
> Total public hourly burden for conducting the activities covered by this ICR ranges between 2.47 and 523.50 hours per respondent annually. Note that most of the public hourly burden comes from recordkeeping activities associated with the acquisition and setting up of electronic record retention systems (i.e., 487.50 hours). EPA believes that only a small number of respondents will undertake these activities (i.e., 428 facilities per year). Therefore, the majority of respondents are expected to be in the lower end of the public burden range.[6]

The preamble indicates that the CROMERRR electronic recordkeeping provisions would have net negative benefits, a highly unusual circumstance for a proposed rule:

> The average annual cost to implement a new electronic record keeping system is $40,000 for each facility, and the net average annual cost savings for operating the record keeping system is $23,000 . . . . Therefore, our estimates indicate that . . . **facilities may not find it cost-effective to develop an electronic records system** unless it addresses both EPA and non-EPA business purposes.[7]

EPA's own cost-benefit analysis report is even more explicit that the electronic recordkeeping provisions would have negative net benefits:

> **Electronic record keeping will likely be advantageous only to organizations that already use it for other reasons.** Unlike electronic reporting, **there are large system costs unique to electronic record keeping. The savings of reduced paper storage and handling are more than offset by the cost of the electronic systems.** In addition, electronic record keeping may put facilities at legal risk. If facilities report electronically but continue to record by paper, they will be conforming to traditional practices in responding to audits, inspections, and enforcement queries and actions. However, inadequately or improperly implementing electronic record keeping creates a risk of being out of compliance.[8]

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[4] Supporting Statement at 13.
[5] Supporting Statement at 30. In contrast, EPA estimates that 324,370 facilities would mail to EPA the registration agreement for electronic reporting. Exhibit 1, Supporting Statement at 33.
[6] Supporting Statement at 31.
[7] 66 Fed. Reg. at 46178 (emphasis added).
[8] Logistics Management Institute, "Cross-Media Electronic Reporting and Records Rule Cost-Benefit Analysis (Mar. 2001) ("Cost-Benefit Analysis") at p. 3-9 (emphasis added).

Accordingly, by EPA's own analysis, the CROMERRR recordkeeping provisions can be justified only as a voluntary program. As shown below, however, those provisions would prove in practice to be anything but voluntary.

2. The CROMERRR Recordkeeping Provisions Would Not Be Voluntary.

While electronic reporting would be voluntary, electronic recordkeeping is not. It is already an integral aspect of how industry today collects and manages data, including data required to meet EPA recordkeeping requirements. As a result, it is not "voluntary" to choose to use electronic recordkeeping; industry has no choice but to utilize electronic recordkeeping.

a. CROMERRR Itself Indicates That Electronic Recordkeeping Would Not Be Voluntary.

The EPA Supporting Statement explains:

> Under section 3.100(a) [of CROMERRR], an electronic record or electronic document will satisfy a recordkeeping requirement under Title 40 only if it is generated and maintained by an acceptable electronic record-retention system as specified under section 3.100(b).[9]

Thus, if a record required by an EPA recordkeeping requirement should qualify as an "electronic record", the full panoply of requirements summarized in section 3.100(b) would apply.

In practical effect, most records generated to meet EPA recordkeeping requirements would qualify as an "electronic record". Proposed § 3.3 would define that term as:

> **any** combination of text, graphics, data, audio, pictorial, or other information represented in digital form that is created, modified, maintained, archived, retrieved **or** distributed by a computer system.[10]

This definition means that if data responsive to EPA recordkeeping requirements are collected on a computer system, the data are considered electronic records, regardless of whether they are maintained electronically or printed out. Any one of the six verbs in the definition is sufficient by itself to trigger the CROMERRR recordkeeping requirements. Immediately upon creation, computer data is an electronic record. Printing out the data later would have no effect on its status as an electronic record.

Conceivably, EPA could amend CROMERRR to make printing out an electronic record a means of avoiding CROMERRR's recordkeeping provisions. Doing so would create a

[9] Supporting Statement at 7.
[10] 66 Fed. Reg. at 46189 (emphasis added).

powerful incentive to avoid those provisions by printing out data which otherwise would not be printed out, and then maintaining that printed data. This would result in a significant loss of efficiency, since much of the utility of electronic data is that it is electronic. It would also result in much more, not less, government-mandated paperwork.

Today, facilities use computers on a daily basis to collect information mandated by EPA recordkeeping requirements. Information on emissions and effluent data can only be collected by computer. Laboratory analysis required to identify chemical species can only be conducted using electronic instruments. The very large amounts of data which must be kept, either to support summary reports to EPA or simply to meet recordkeeping requirements, cannot be managed without the use of computers. This is true both for large facilities and small ones. There is virtually no facility which is subject to EPA recordkeeping requirements that does not utilize computers to meet those requirements. It is not "voluntary" to utilize electronic recordkeeping; it is essential.

A single example will illustrate the kinds of data required by EPA recordkeeping provisions which can only be collected by computer and which, in practical terms, would be retained on a computer rather than in printed form. Here is one paragraph from the general reporting and continuous records provision of the NESHAP for the synthetic organic chemical manufacturing industry for process vents, storage vessels, transfer operations, and wastewater, 40 CFR § 63.152(f):

> (f) Owners or operators required to keep continuous records by §§ 63.118, 63.130, 63.147, 63.150, or other sections of this subpart shall keep records as specified in paragraphs (f)(1) through (f)(7) of this section, unless an alternative recordkeeping system has been requested and approved under § 63.151(f) or (g) or § 63.152(e) or under § 63.8(f) of subpart A of this part, and except as provided in paragraph (c)(2)(ii)(C) of this section or in paragraph (g) of this section. If a monitoring plan for storage vessels pursuant to § 63.120(d)(2)(i) requires continuous records, the monitoring plan shall specify which provisions, if any, of paragraphs (f)(1) through (f)(7) of this section apply.
>
> (1) The monitoring system shall measure data values at least once every 15 minutes.
>
> (2) The owner or operator shall record either:
>
> (i) Each measured data value; or
>
> (ii) Block average values for 15-minute or shorter periods calculated from all measured data values during each period or at least one measured data value per minute if measured more frequently than once per minute.
>
> (3) If the daily average value of a monitored parameter for a given operating day

is within the range established in the Notification of Compliance Status or operating permit, the owner or operator shall either:

(i) Retain block hourly average values for that operating day for 5 years and discard, at or after the end of that operating day, the 15-minute or more frequent average values and readings recorded under paragraph (f)(2) of this section; or

(ii) Retain the data recorded in paragraph (f)(2) of this section for 5 years.

(4) If the daily average value of a monitored parameter for a given operating day is outside the range established in the Notification of Compliance Status or operating permit, the owner or operator shall retain the data recorded that operating day under paragraph (f)(2) of this section for 5 years.

(5) Daily average values of each continuously monitored parameter shall be calculated for each operating day, and retained for 5 years, except as specified in paragraphs (f)(6) and (f)(7) of this section.

(i) The daily average shall be calculated as the average of all values for a monitored parameter recorded during the operating day. The average shall cover a 24-hour period if operation is continuous, or the number of hours of operation per operating day if operation is not continuous.

(ii) The operating day shall be the period defined in the operating permit or the Notification of Compliance Status. It may be from midnight to midnight or another daily period.

(6) If all recorded values for a monitored parameter during an operating day are within the range established in the Notification of Compliance Status or operating permit, the owner or operator may record that all values were within the range and retain this record for 5 years rather than calculating and recording a daily average for that operating day. For these operating days, the records required in paragraph (f)(3) of this section shall also be retained for 5 years.

(7) Monitoring data recorded during periods identified in paragraphs (f)(7)(i) through (f)(7)(v) of this section shall not be included in any average computed under this subpart. Records shall be kept of the times and durations of all such periods and any other periods during process or control device operation when monitors are not operating.

(i) Monitoring system breakdowns, repairs, calibration checks, and zero (low-level) and high-level adjustments;

(ii) Start-ups;

(iii) Shutdowns;

(iv) Malfunctions;

(v) Periods of non-operation of the chemical manufacturing process unit (or portion thereof), resulting in cessation of the emissions to which the monitoring applies.

Many other examples could be provided of recordkeeping requirements which in practice can only be met with the use of computers.

Each facility using a computer to keep EPA-mandated records would be subject to CROMERRR's electronic recordkeeping requirements upon promulgation of CROMERRR. EPA's estimate of 428 facilities annually choosing to conduct electronic recordkeeping has no relation to the actual number of affected facilities. EPA's Cost-Benefit Analysis estimates that there are 1.2 million facilities subject to EPA reporting requirements.[11] It is reasonable to assume that all of them are also subject to EPA recordkeeping requirements. It is also reasonable to assume that virtually all of them utilize computers to meet those requirements, at least in part. Since such use of computers is sufficient to trigger CROMERRR's recordkeeping requirements, it is reasonable to estimate the number of facilities affected by those provisions is 1.2 million.

Accordingly, CROMERRR is apparently not really "voluntary" at all. In today's electronic age, most regulated entities have no choice but to collect and store data on a computer, and that would seem to be enough to make CROMERRR recordkeeping provisions apply. The result would be that all or most entities subject to EPA recordkeeping requirements, an estimated 1.2 million facilities, would have adapt their computer systems to meet CROMERRR requirements.

b. <u>Experience With FDA's Rule Corresponding to CROMERRR Indicates That CROMERRR's Recordkeeping Provisions Would Not Be Voluntary.</u>

To understand how CROMERRR would work in practice, it is helpful to refer to the FDA rule which corresponds to CROMERRR, 21 CFR Part 11. (EPA indicated that CROMERRR requirements "are intended to be consistent with criteria set forth for electronic document systems in other relevant regulations, such as FDA's criteria in 21 CFR part 11."[12] A comparison of CROMERRR and 21 CFR Part 11 shows that EPA closely modeled CROMERRR on the earlier FDA rule.)

[11] Cost-Benefit Analysis at p. 3-3.
[12] 66 Fed. Reg. at 46170.

The FDA rule issued in 1997.[13] Its definition of "electronic record"[14] is virtually identical to the corresponding definition in CROMERRR, and the substantive provisions are similar. Like the CROMERRR preamble, the FDA preamble declared that the recordkeeping provisions were voluntary, stating "The use of electronic records as well as their submission to FDA is voluntary."[15] Similarly, it declared:

> The agency emphasizes that these regulations do not require, but rather permit, the use of electronic records . . . . Firms not confident that their electronic systems meet the minimal requirements of these regulations are free to continue to use . . . paper documents to meet recordkeeping requirements.[16]

This apparent voluntariness, however, masked a practical effect of making any agency-mandated records which are electronic at some point into electronic records subject to the rule. The preamble went on to indicate in comment 22 that in most cases paper records created by computer would be considered electronic records covered by 21 CFR Part 11:

> One comment asked whether paper records created by computer would be subject to proposed part 11. The comment cited, as an example, the situation in which a computer system collects toxicology data that are printed out and maintained as "raw data." Part 11 is intended to apply to systems that create and maintain electronic records under FDA's requirements in Chapter I of Title 21, **even though some of those electronic records may be printed on paper at certain times** . . . . When records intended to meet regulatory requirements are in electronic form, part 11 would apply to all the relevant aspects of managing those records (including their creation, signing, modification, storage, access, and retrieval.)[17]

That preamble comment did create a limited exception for word processing documents:

> Part 11 is not intended to apply to computer systems that are merely incidental to the creation of paper records that are subsequently maintained in traditional paper-based systems. **In such cases, the computer systems would function essentially like manual typewriters or pens** and any signatures would be traditional handwritten signatures.[18]

Significantly, the CROMERRR preamble contains no similar "typewriter" exception, suggesting that even word processing documents would be considered electronic records subject to CROMERRR.

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[13] 62 Fed. Reg. 13430 (Mar. 20, 1997).
[14] 21 CFR § 11.3(b)(6).
[15] 62 Fed. Reg. at 13430.
[16] 62 Fed. Reg. at 13434.
[17] 62 Fed. Reg. at 13437 (emphasis added).
[18] 62 Fed. Reg. at 13437 (emphasis added).

Subsequent FDA interpretations of 21 CFR Part 11 further indicated FDA's intention that the literal words of the definition of "electronic record" were enough to subject data ever in electronic form to the Part 11 requirements:

Q: Can a firm that creates batch records in electronic form archive them as paper only?

A: No. Part 11 requires that electronic records be archived in electronic form .... It is important to note that paper printouts are seldom accurate and complete copies of electronic records (paper copies lack meta-data information such as time and date stamps, audit trails, and other information not intended to be printed.)[19]

Q: Will the electronic signature rule apply to Toxicology LIMS type systems ... that are capturing data from several different sources such as analytical instruments, scales, and technologist direct data entry?

A: Yes. The rule applies to all these systems ....

Q: If analytical instruments are computerized ..., will the electronic signature rule apply when GLP data are created and maintained electronically?

A: Yes—again, the electronic records capability.

Q: If a computer system creates/collects data which is later printed out and signed, does the electronic signature rule apply?

A: Yes—these regs do apply. Don't think you can evade these regs by printing everything out. The only exception is using a system as a typewriter—like a word processor. Once you create an electronic record, part 11 applies. You will not be able to say the official copy is the paper, but the electronic copy is the working one—this will not work. A paper print out is not necessarily an accurate record—industry should decide that the raw data is the electronic media when it is collected originally to electronic media.[20]

Q: What is an 'electronic record'? ... Some people feel that data which is collected and manipulated by a computer system may be considered a 'paper record' as long as it is printed out and the paper copy is retained. We have created a table of cases below. Please indicate, on a case by case basis, whether the data on the computer system is considered a true 'electronic record' (and therefore subject to the requirements of the new rule) or if it is considered a 'paper record'....

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[19] FDA, "Human Drug CGMP Notes", Vol. 6. No. 3 (Sept. 1998) at 6, available at www.fda.gov/cder/hdn/cnotes98.htm.

[20] Notes by Karen Raskasky, "SQA CVIC Meeting 6/10/97 with Paul Motise (FDA Computer Expert Inspector—Project Leader on the Electronic Signatures Regs)", available at www.raskaskygroup.com/motise.html.

A: In all of the cases in the table you provided, the electronic record is created to meet an FDA requirement and part 11 applies. **Folks should be careful about relying upon paper printouts as a means of evading part 11.** We addressed this issue fully in comment 22. **Lab information systems, manufacturing process systems and the like are far more than mere word processors. Data collected and manipulated electronically to meet an FDA record requirement is an electronic record.** . . . The basic trustworthiness and reliability of the table records depends heavily on the trustworthiness and reliability of the corresponding electronic systems. In addition, paper printouts of the records in the table are not likely to be accurate and complete copies of the electronic records they represent.[21]

In summary, FDA has interpreted its version of CROMERRR, which is quite similar to CROMERRR in relevant respects, to apply the rule to all records mandated by FDA regulations which are generated or maintained electronically at any point in their lifetimes, even if the records are printed out at some point and the paper records subsequently handled as the "official" records. The only exception recognized by FDA is for word processing documents. CROMERRR does not even make that exception.

FDA estimates that Part 11 recordkeeping requirements apply to 4,500 facilities.[22] Given that FDA affects only a tiny fraction of the facilities regulated by EPA, the estimate of 1.2 million facilities that would be affected by CROMERRR appears to be reasonable.

c. Summary

Under CROMERRR, keeping agency-mandated records electronically is "voluntary", but doing so would subject the facility keeping the records to the rule. In modern practice, agency-mandated records are almost always created or maintained or manipulated electronically, at least at some point in their lifetimes. Under the literal words of CROMERRR and 21 CFR Part 11, and under FDA interpretations of Part 11, such records would be considered to be "electronic records" and be subject to the rule.

Since it is very difficult to escape the use of "electronic records", as interpreted above, CROMERRR would effectively be mandatory for many EPA-required records which are electronic at any point in their lifetimes. Such recordkeeping requirements are in fact not "voluntary" except in the most highly technical sense. In a practical sense, they are mandatory. Some 1.2 million facilities would be subject to those requirements.

3. Since CROMERRR's Recordkeeping Provisions Would Not Be Voluntary, the EPA Burden Estimates Are Unreliable.

[21] Pharmaceutical Research and Manufacturers of America, "FDA Response to PhRMA CSVC Questions, Part IV" at 1-3 (June 24, 1997) (emphasis added).
[22] Request for comments on ICR on Part 11, 65 Fed. Reg. 18111 (Apr. 6, 2000)..

The EPA estimates of the paperwork burdens to be imposed by the CROMERRR recordkeeping requirements assumed that only 428 facilities would be subject to those requirements annually. As shown above, a better assumption would be that 1.2 million facilities would be affected. Accordingly, the EPA burden estimates are not off by percentages, but rather are off by several orders of magnitude.

OMB should request EPA to conduct a new paperwork burden analysis. If it chooses to pursue CROMERRR as presently configured, EPA should then submit a new ICR. Dow believes that instead EPA should withdraw CROMERRR and rework it substantially.

4. Since CROMERRR's Recordkeeping Provisions Would Not Be Voluntary, EPA Has Not Addressed the Effect on Small Business.

Under both Executive Order 12866 and the Regulatory Flexibility Act ("RFA"), EPA must regulate with consideration of the impact on small businesses. The EPA Supporting Statement purports to address the effect of CROMERRR on small businesses:

> Electronic reporting and recordkeeping is voluntary . . . . These changes will reduce the burden on all affected entities, including small businesses.[23]

The CROMERRR preamble asserted, "Today's rule is not subject to the RFA because electronic reporting and recordkeeping is voluntary."[24]

As explained above, however, any small business which utilizes a computer to help it meet EPA recordkeeping requirements would incur the significant costs of complying with the CROMERRR recordkeeping requirements. That includes virtually all small businesses subject to those requirements.

OMB should direct EPA to conduct a Regulatory Flexibility Analysis on the impact of CROMERRR recordkeeping requirements on small business.

5. Since CROMERRR Would Not Be Voluntary, EPA Has Effectively Amended Many EPA Recordkeeping Requirements.

EPA maintains that "the proposed rule would not amend reporting or recordkeeping requirements under existing regulations and statutes".[25] In practical effect, however, CROMERRR would radically alter current recordkeeping practices allowed under existing EPA regulations.

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[23] Supporting Statement at 23.
[24] 66 Fed. Reg. at 46186.
[25] Supporting Statement at 13.

CROMERRR would provide that electronic recordkeeping could not be used to meet EPA recordkeeping requirements unless "EPA has published a notice in the Federal Register announcing that EPA is prepared to recognize electronic records under the named Part or Subpart of this Title."[26] The apparent import of this provision is to prohibit any electronic recordkeeping until EPA publishes such a notice, which it has not yet done.

Yet some EPA regulations explicitly allow electronic recordkeeping today. For example, the general recordkeeping provision of the NESHAPs regulations under the Clean Air Act provides:

> **Such files may be maintained** on microfilm, **on a computer**, on computer floppy disks, on magnetic tape disks, or on microfiche.[27]

EPA has many other regulations explicitly authorizing electronic recordkeeping.[28]

Other EPA regulations are media-neutral as to how required records must be kept, and thus they implicitly authorize electronic recordkeeping. Some are silent on how records are to be kept, while others explicitly allow any accurate format. For example, EPA's GLP regulations provide:

> Records required by this part may be retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records.[29]

CROMERRR would have the effect of prohibiting electronic recordkeeping, now authorized explicitly or implicitly in many current EPA regulations, until (1) EPA published a notice authorizing electronic recordkeeping to begin, and (2) regulated facilities met the CROMERRR requirements for electronic recordkeeping.

Thus, CROMERRR would effectively amend many EPA recordkeeping regulations to prohibit recordkeeping practices acceptable today.

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[26] Proposed 40 CFR § 3.2(b)(2), 66 Fed. Reg. at 46189; see also 66 Fed. Reg. at 46167.
[27] 40 CFR § 63.10(b)(1).
[28] See, e.g., 40 CFR § 60.58c(f); 40 CFR § 60.59a(b)(2)(i); 40 CFR § 60.59b(k); 40 CFR § 60.2180; 40 CFR § 60.2745; 40 CFR § 62.14462; 40 CFR § 63.103(c)(1); 40 CFR § 63.104(c)(3); 40 CFR § 63.152(g)(1)(vi)(D); 40 CFR § 63.181(a); 40 CFR § 63.192(f)(1); 40 CFR § 63.506(a)(1); 40 CFR § 63.642(e) 40 CFR § 63.774(b)(1)(ii); 40 CFR § 63.850(e)(2); 40 CFR § 63.998(b)(5)(i)(F)(*4*); 40 CFR § 63.1065; 40 CFR § 63.1109(c); 40 CFR § 63.11.92(d); 40 CFR § 63.1255(g)(1); 40 CFR § 63.1284(b)(1)(iv); 40 CFR § 63.1335(a)(1); 40 CFR § 63.1355(a); 40 CFR § 63.1363(g)(1); 40 CFR § 63.1386(d)(1)(ii); 40 CFR § 63.1409(c)(3); 40 CFR § 63.1416(a)(1); 40 CFR § 63.1439(a); 40 CFR § 63.1517(a)(2); 40 CFR § 63.5770(d); 40 CFR § 64.9(b)(2); 40 CFR § 65.4(c)(3); 40 CFR § 65.161(e)(1)(vi)(D); 40 CFR § 85.1806(e); 40 CFR § 85.1904(d). This is only a partial list of the regulations under the Clean Air Act explicitly authorizing electronic recordkeeping.
[29] 40 CFR § 160.195(i); 40 CFR § 792.195(i).

6. EPA's Per-Facility Burden Estimate for CROMERRR's Recordkeeping Provisions Is Off by Orders of Magnitude.

a. EPA Predicts That Recordkeeping Costs Would Be "Very Significant".

EPA's Supporting Statement estimates a capital cost of $25,000 per facility to acquire and set up a recordkeeping system meeting CROMERRR requirements, another $15,000 in labor costs for that activity, and annual costs thereafter of $17,000 per facility.[30] The Cost-Benefit Analysis concludes that "These costs are very significant."[31] The preamble indicates that EPA recognizes that those costs are excessive:

> EPA is continuing to research electronic record-keeping options that will improve the cost-effectiveness of electronic record-keeping while meeting federal enforcement requirements.[32]

Nevertheless, experience with FDA's counterpart to CROMERRR indicates that EPA's per-facility cost estimates are unrealistically low. (It should be noted that EPA's cost estimates, derived from the Cost-Benefit Analysis, include no background on how the costs were estimated. The Cost-Benefit Analysis simply states that its estimates are based on "our review of commercial systems".[33])

b. CROMERRR Would Impose Substantial Recordkeeping System Requirements.

CROMERRR would impose substantial anti-fraud provisions that most current computer systems simply do not have. These requirements would apply both to new systems and to existing systems. There would apparently be no grandfathering of legacy systems under CROMERRR, as there is none under Part 11. As FDA explained:

> The agency believes that . . . a general exemption for existing systems that do not meet these provisions would be inappropriate and not in the public interest . . . .[34]

> As explained in the preamble to the final rule, Part 11 does not grandfather legacy systems and FDA expects that firms using legacy systems will begin taking steps to achieve full compliance.[35]

CROMERRR and 21 CFR Part 11 share the following core requirements, among others:[36]

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[30] Exhibit 1, Supporting Statement at 33.
[31] Cost-Benefit Analysis, p. 3-7.
[32] 66 Fed. Reg. at 46179.
[33] Cost-Benefit Analysis at p. 3-7.
[34] 62 Fed. Reg. at 13434.
[35] 64 Fed. Reg. 39146, 39147 (July 21, 1999).

- Generate and maintain accurate and complete electronic records in a form that may not be altered without detection.
- Maintain all electronic records without alteration for the entirety of the required period for record retention. While many EPA recordkeeping requirements have retention periods of five years or less, some have longer periods. For example, the record retention period for the FIFRA Good Laboratory Practice regulations is for the life of the pesticide registration, which could last decades.[37] Given the changes in both software and hardware that will occur over time, maintaining legacy systems or transitioning the data accurately across multiple generations of computer systems is very difficult.
- Produce accurate and complete copies of any electronic record and render these available, in both human readable and electronic form, for on-site inspection and off-site review, for the entirety of the record retention period.
- Use secure, computer-generated, time-stamped audit trails that automatically record the date and time of operator entries and actions that create, modify, or delete electronic records. Many computer systems and software lack this capability. For example, Microsoft Excel® lacks an audit trail capability, and apparently could not be used without an expensive (and potentially problematic) add-on feature.[38]
- Ensure that record changes do not obscure previously recorded information and that audit trail information is retained for at least the record retention period to be available for agency review.
- Archive electronic records in an electronic format which preserves the context, meta data, and audit trail. If necessary, ensure that complete records can be transferred to a new system including related meta data.

These are very challenging requirements, as recognized by federal agencies considering adoption of such requirements for their internal records. For example, the need to preserve records electronically for long periods elicited these comments:

> The long-term preservation and retention of those electronic records is a challenge because software products change frequently. The Department of Health and Human Services, in its comments to OMB's initial draft guidance for GPEA, expressed concerns about obsolescence of hardware and software, and NARA, in its guidance, remarked that this obsolescence can make record retention burdensome. The NARA guidance developed in response to the GPEA also recognizes that records management involving records that have been created using electronic signature technology is a complex process, requiring training and

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[36] Compare 21 CFR Part 11, Subpart B with proposed 40 CFR Part 3, Subpart C, 66 Fed. Reg. at 46190.
[37] 40 C.F.R. § 160.195(b)(1).
[38] See, e.g., www.fda.gov/ohrms/dockets/dockets/00d1543/mm0001_01.htm (alternatively, see entry for 3/23/01 at www.fda.gov/ohrms/dockets/dockets/00d1541/00d1541.htm) (report of vendor presentation to FDA of proprietary software purportedly able to add an audit trail feature to Excel); fuller description at www.wimmersystems.com.

knowledge on the part of both IT specialists and records management personnel at the agencies. The guidance points out that in systems implemented as a result of GPEA, records management requirements will be an important element of the IT system requirements.[39]

Similarly, the Justice Department has advised federal agencies considering electronic recordkeeping systems of their own:

> Agencies should consider several factors related to the accessibility of electronic records. First, computer technology is rapidly changing and software and formatting standards may quickly become obsolete. Computer-stored data may become useless unless the agency can provide the continued capability with the older technologies or can accurately translate the document as more modern systems are implemented. Second, if in the future, an agency no longer has staff who are familiar and competent to work with the electronic processes necessary to read older data, such data could be functionally unavailable. Electronic files might be stored while encrypted by software or protected by passwords no longer available or remembered years later, unless steps are taken to preserve the software or passwords.[40]

Government agencies faced with the cost of installing electronic recordkeeping systems are well aware of the potentially immense costs involved:

> Several agencies emphasized that GPEA-related initiatives will be costly to implement. They expressed concern about securing funds for the many efforts involved, such as updating network plans, conducting risk analyses, evaluating technology alternatives, procuring and installing recordkeeping software, and testing networks. The Social Security Administration (SSA) noted in comments to OMB's initial draft guidance for GPEA implementation that implementing GPEA could cost SSA over $40 million and run past the year 2005 if SSA were to include full electronic processing of transactions in its efforts.[41]

A number of software vendors have approached FDA with information asserting that their products can address certain aspects of Part 11 compliance.[42] A few vendors claim

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[39] Government Accounting Office, "Electronic Government: Government Paperwork Elimination Act Presents Challenges for Agencies", GAO/AIMD-00-282 (Sept. 2000), available at www.gao.gov/new.items/ai00282.pdf.

[40] Department of Justice, "Legal Considerations in Designing and Implementing Electronic Processes: A Guide for Federal Agencies" (Nov. 2000), available at www.cybercrime.gov/eprocess.htm, § II.A.3 (footnote omitted)

[41] Government Accounting Office, "Electronic Government: Government Paperwork Elimination Act Presents Challenges for Agencies", GAO/AIMD-00-282 (Sept. 2000), available at www.gao.gov/new.items/ai00282.pdf

[42] See generally www.fda.gov/ora/compliance_ref/part11/dockets_index.htm; www.21cfrpart11.com/solution_providers.htm.

that their products can achieve complete Part 11 compliance, when implemented with appropriate training and procedures.

The point is that every regulated entity subject to CROMERRR would apparently have to purchase thousands to millions of dollars of add-ons to existing systems and/or purchase new computer systems, just a short time after Y2K caused widespread replacement or upgrading of computer systems. EPA's cost estimates do not address these compliance costs.

c. The Corresponding FDA Rule Costs Millions of Dollars.

It should be noted that FDA similarly estimated that its rule would have little financial impact:

> The activities regulated by this rule are voluntary; no entity is required by this rule to maintain or submit records electronically if it does not wish to do so. Presumably, no firm (or other regulated entity) will implement electronic recordkeeping unless the benefits to that firm are expected to exceed any costs (including capital and maintenance costs). Thus, the industry will incur no net costs as a result of this rule.[43]

Yet the pharmaceutical industry has found that Part 11 compliance is costly indeed:

> By anyone's measure, Part 11 was a surprise to the health care manufacturing industry . . . . [T]he section of Part 11 that dealt with electronic records was anything but benign . . . . **This is a big deal, impacting literally thousands of legacy systems in the regulated industry.**[44]

> Although the Agency concluded that the Regulation will not have significant economic impact, PhRMA companies are estimating the financial impact to be significantly higher than the cost of resolving any Y2K problems . . . . In one case, **it cost $600,000 to bring a chromatography system into compliance.** One large company has estimated that **archiving a complex electronic system would cost them in excess of ten million dollars** over the retention period. The cost to fully comply with the Regulation is expected to **exceed $150 million** for a large pharmaceutical company.[45]

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[43] 62 Fed. Reg. at 13462.

[44] Nick A. Dayton, Ph.D., Director of Quality Assurance, Hospital Products Division, Abbott Laboratories, "A Practical Approach to Compliance for 21 CFR Part 11" (1999) (emphasis added), available at www.ivthome.com/free/21cfr.htm.

[45] Pharmaceutical Research and Manufacturers of America, "21 CFR Part 11: A Partnership Approach to Achieving Regulatory Compliance for Electronic Records and Signatures" (Nov. 30, 1999) (emphasis added), available at www.fda.gov/ohrms/dockets/dailys/120899/c0004.pdf.

> [T]he extensive experience that has now been gained from attempting to implement [Part 11] within the regulated industries has highlighted a number of difficulties giving rise to significant costs and risks that may outweigh the benefits .... **Companies are investing millions of dollars in "good faith" efforts to comply with the Regulation.**[46]

One consultant estimated the costs for compliance with 21 CFR Part 11 in the millions of dollars.[47]

d. Summary

Again, there is a fundamental disconnect between EPA's conception of the burden associated with CROMERRR's recordkeeping provisions and what FDA's counterpart to CROMERRR is currently costing the pharmaceutical industry. EPA's per-facility burden estimates, while presenting "very significant" costs, do not begin to address the costs of CROMERRR. OMB should recognize that federal agencies coping with GPEA compliance have each budgeted millions of dollars to implement computer systems capable of storing electronic records so as to meet goals such as those mandated by CROMERRR. Regulated entities would have lesser costs, but still costs potentially in the millions of dollars.

OMB should deny the ICR and direct EPA to begin again on its cost estimates.

7. EPA Apparently Failed to Conduct a Risk Assessment and Cost-Benefit Analysis on the Need for Stringent Anti-Fraud Provisions in CROMERRR; Had It Done So, Less Stringent Provisions Might Have Been Found Adequate.

CROMERRR is EPA's response to the GPEA, which directs OMB to issue guidance to Executive Branch agencies on GPEA implementation. EPA apparently did not follow the OMB guidance to conduct a risk assessment and cost-benefit analysis on the need for anti-fraud provisions. If it had done so, it might have found insufficient justification for the stringent and expensive provisions included in CROMERRR. Much less stringent provisions might have been adequate.

a. OMB Guidance Directs EPA to Conduct a Risk Assessment and Cost-Benefit Analysis on the Need for Stringent Anti-Fraud Provisions.

[46] Industry Coalition on 21 CFR Part 11, "Recommendations for Achieving Compliance with the e-Records and e-Signatures Regulation" (Aug. 29, 2000) (emphasis added), available at www.fda.gov/ohrms/dockets/dockets/00d1539/00d1539.htm.

[47] The Hollis Group, "Financial Impact of 21 CFR 11 and Its Interpretations" (Sept. 22, 1998), available at www.hollisgroup.com/downloads/21%20cfr%2011%20costs.ppt.

The GPEA is an enabling statute, designed to encourage (not discourage) electronic reporting and recordkeeping. With respect to electronic recordkeeping it provides:

> Electronic records submitted or maintained in accordance with procedures developed under this Act . . . shall not be denied legal effect, validity, or enforceability because such records are in electronic form.[48]

OMB has issued guidance to Executive Branch agencies, including EPA, on how to implement the GPEA.[49] That guidance calls for each agency to conduct a risk assessment and cost-benefit analysis:

> Accordingly, agencies should develop and implement plans, supported by an assessment of whether to use and accept documents in electronic form and to engage in electronic transactions. The assessment should weigh costs and benefits and involve an appropriate risk analysis, recognizing that low-risk information processes may need only minimal consideration, while high-risk processes may need extensive analysis.[50]

[48] GPEA, § 1707.
[49] 65 Fed. Reg. 25508 (May 2, 2000).
[50] 65 Fed. Reg. at 25513.

b. EPA Apparently Failed to Conduct a Risk Assessment, Instead Choosing a "One Size Fits All" Approach.

EPA apparently did not conduct either a risk assessment or cost-benefit analysis of differing sets of security provisions. Instead, it seems to have concluded that there was a high need for rigorous provisions to deter or punish fraud in connection with all EPA-mandated recordkeeping requirements:

> For both document submission and record-keeping, the point of the proposed requirements is primarily to ensure that the authenticity and integrity of these documents and records are preserved as they are created, submitted, and/or maintained electronically, so that they continue to provide strong evidence of what was intended by the individuals who created and/or signed and certified them. Among other things, today's proposal is intended to ensure that the federal laws regarding the falsification of information still apply to any and all electronic transactions, and that fraudulent electronic submissions or record-keeping can be prosecuted to the fullest extent of the law. In establishing clear requirements for electronic reporting systems and electronic records, this proposed rule will help to minimize fraud by assuring that the responsible individuals can be readily identified.[51]

Note that these anti-fraud provisions would be on top of existing anti-fraud provisions. The federal criminal code already prohibits making a false statement to the government or keeping fraudulent records required by the government.[52] Most or all EPA-administered statutes contain specific prohibitions on making false statements or keeping false records.[53]

c. A Risk Assessment and Cost-Benefit Analysis Might Have Shown That CROMERRR's Anti-Fraud Provisions Are Excessive.

The OMB guidance suggests that if EPA had conducted a risk assessment and cost-benefit analysis, it might have found that its concerns with fraud in electronic recordkeeping were excessive:

> Setting up a very secure, but expensive, automated system may in fact buy only a marginal benefit of deterrence or risk reduction over other alternatives and may not be worth the extra cost. For example, **past experience with fraud risks, and a careful analysis of those risks, shows that exposure is often low.** If this is the case a less expensive system that substantially deters fraud is warranted, and not an absolutely secure system. Overall, security determination should conform with

[51] 66 Fed. Reg. at 46164.
[52] 18 U.S.C. § 1001.
[53] See, e.g., TSCA § 16(b), 15 U.S.C. § 2615(b); FIFRA §§ 12(a)(2)(M), (Q), (R), 7 U.S.C. §§ 136j(a)(2)(M), (Q), (R).

> the Computer Security Act: the level of security should be commensurate with the level of sensitivity of the transaction.[54]

Instead, following FDA's example, EPA apparently assumed that all EPA-mandated records, regardless of their nature, have the highest level of sensitivity. The OMB guidance cautions against this "one size fits all" approach:

> Agencies should also keep in mind that GPEA specifically states that electronic records and their related electronic signatures are not to be denied legal effect, validity, or enforceability merely because they are in electronic form. **We are not, therefore, prescribing "one size fits all" requirements applicable to transactions regardless of sensitivity.**[55]

In particular, the OMB guidance advises that the risk of fraud is lowest where there is an ongoing relationship, as with EPA and regulated entities:

> Risks tend to be relatively low in cases where there is an ongoing relationship between the parties. Generally speaking . . . , **transactions between a regulatory agency and a publicly traded corporation or other known entity regulated by that agency can often bear a relatively low risk of repudiation or fraud,** particularly where the regulatory agency has an ongoing relationship with, and enforcement authority over, the entity.[56]

EPA keeps careful track of its regulated entities, routinely inspects them, and deals with them on an ongoing basis. Accordingly, the risk of fraud is probably quite low.

In contrast to EPA and FDA, other federal agencies implementing the GPEA have chosen to adjust the degree of anti-fraud protections to the risk of fraud and the consequences of fraud. For example, the Treasury Department has adopted policies and practices for the use of electronic transactions and authentication techniques in federal payments and collections.[57] It uses a risk-based approach:

> All payment, collection, and collateral transactions must be properly authenticated, in a manner commensurate with the risks of the transaction.[58]

Transactions with negligible risk may occur without any electronic authentication technique. Those with low risk must use a single factor authentication, such as a personal identification number. Those with moderate or high risk would require more in the way of authentication, such as cryptography.

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[54] 65 Fed. Reg. at 25515 (emphasis added).
[55] 65 Fed. Reg. at 25510 (emphasis added).
[56] 65 Fed. Reg. at 25517 (emphasis added).
[57] 66 Fed. Reg. 394 (Jan. 3, 2001).
[58] 66 Fed. Reg. at 396.

The actions of other agencies suggest that EPA can address the deterrence and detection of fraud in recordkeeping requirements in a risk-based manner. There is no indication in CROMERRR that EPA has done so.

8. EPA Has Not Focused Sufficiently on Electronic Recordkeeping.

EPA has placed virtually nothing in the rulemaking docket on the impact of CROMERRR's electronic recordkeeping provisions on regulated facilities. There is information on the impact of CROMERRR on EPA's own recordkeeping systems, and the impact of CROMERRR's reporting provisions on regulated facilities, but there is next to nothing on electronic recordkeeping by regulated facilities. This reflects EPA's focus on reporting, not recordkeeping.

EPA maintains that electronic reporting, not electronic recordkeeping, is the main point of CROMERRR:

> For practical purposes, the most important changes that the proposed rule makes to current policy is in EPA's technical approach to electronic reporting.[59]

Yet electronic reporting is clearly voluntary. As shown above, in the modern world, electronic recordkeeping is not. EPA has mistakenly assumed that few facilities would be affected by CROMERRR, and therefore little regulatory analysis of CROMERRR's recordkeeping requirements was needed. In reality, CROMERRR's reporting provisions are of much lesser importance that its recordkeeping provisions.

The difference is between a voluntary program and a mandatory one. Regulated facilities can choose whether or not to report electronically, and thereby gain or forgo the efficiencies of electronic reporting, but with knowledge that to gain those advantages they must pay the cost of meeting CROMERRR reporting requirements. Regulated facilities cannot choose whether or not to keep records electronically. They are heavily dependent on computers to generate, maintain, and manipulate EPA-required data. They can choose to print out such data, but under CROMERRR printing out data would have no effect on their obligations. Moreover, printing out data is often a futile exercise, since the value of most electronic records lies precisely in their being electronic; resorting to paper copies often would mean loss of significant utility.

Whatever EPA does with respect to the electronic reporting provisions of CROMERRR, it should withdraw the electronic recordkeeping provisions. It should re-propose them, if at all, only after performing in a meaningful fashion the kinds of analysis major regulations now require.

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[59] Supporting Statement at 13.

9. Conclusion

OMB should not approve the ICR for CROMERRR. Instead, it should direct EPA to withdraw the proposed rule, re-think its provisions, perform the required analyses, and only thereafter consider re-proposing an amended version.

Sincerely,

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